Research & Development
182 Susquehanna Ave
Exeter, PA 18643
570-655-5574
FAX 655-2990
www.pridemobility.com

K070950

Exhibit 1

510(k) Summary
Pride Mobility Products Corporation
C5 Lift Chair

APR 16 2007

Submitter's Name & Address:
Pride Mobility Products Corporation
182 Susquehanna Avenue
Exeter, Pa. 18643
Phone: (570) 655-5574
Facsimile: (570) 655-2990

Contact Person:
Thomas Schappert
Official Correspondent

Date Prepared:
03-02-07

Name of Device and Proprietary Name:
C5 Lift Chair / Pride Mobility Products Corporation

Common or Usual Name:
Electric Lift Chair

Classification Name:
Electric Positioning Chair per 21 CFR, 890.3110

Product Code:
INO

Comparison to Predicate Devices:
The **C5 Lift Chair** is substantially equivalent to the Pride Mobility TMR-48 (K953342) when comparing; Construction, Performance, and Stability. The performance characteristics and positioning of components are similar to achieve the same Intended Use. The differences between the **C5 Lift Chair** and the TMR-48 are in the construction materials and electronics.

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Device Description:
The *Pride Mobility* **C5 Lift Chair** is an upholstered chair assembly constructed of a welded steel frame, and foam and fabric compliant to Cal 117 Flammability requirements. The chair is assembled to a welded steel lifting frame mechanism having a 24 VDC motor / actuator powered by standard 110 volt AC power from a wall outlet. A Hand Held Switch Control Device engages the actuators to position the chair to a recline, sitting, or standing position.

Intended Use:
The Intended Use of the Pride Mobility **C5 Lift Chair** is to provide lift assistance for persons who have difficulty rising from a seated position to a standing position.

Non-Clinical Testing:
The Pride Mobility **C5 Lift Chair** was tested to the following Safety Standards:
CAL 117 Sections A, D, & E - Flammability Testing for Upholstered Furniture
EN 61000-6-3, and EN 61000-6-1 – Electromagnetic Emissions & Immunity Tests
EN60601-1 / A2: 1995 / EN60601-1 / A2: 1995 – Medical Electrical Equipment – General Requirements for Safety

Discussion of Clinical Testing Performed:
N/A

Conclusions:
The Pride Mobility **C5 Lift Chair** has the same intended use and similar technological characteristics as the TMR-48 (K953342), moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **C5 Lift Chair** is substantially equivalent to the predicate device, has passed all the necessary testing procedures, and is considered to be safe for user operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pride Mobility Products Corporation
% Mr. Thomas Schappert
182 Susquehanna Avenue
Exeter, Pennsylvania 18643

APR 16 2007

Re: K070950
Trade/Device Name: C5/Electric Positioning Chair
Regulation Number: 21 CFR 890.3110
Regulation Name: Electric positioning chair
Regulatory Class: Class II
Product Code: INO
Dated: March 23, 2007
Received: April 4, 2007

Dear Mr. Schappert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 3

Indications for Use

510(k) Number (if known): K

Device Name: C5 / Electric Positioning Chair

Indications for Use:

The Intended Use of the Pride Mobility **C5 Lift Chair** is to provide lift assistance for persons who have difficulty rising from a seated position to a standing position.

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K070950

Prescription Use X **AND / OR** **Over-The-Counter Use** X
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)